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Comments on the Discussion Draft "Proposals to increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses"

The proposals put forth in this draft document, to increase the number of approved animal drugs for minor use, as a whole should increase the number of approvals for minor species and for minor uses. This would be accomplished principally through increased involvement from the pharmaceutical industry, and also by reduced requirements by other groups producing the required research data, and through increased budgets for completing these types of approvals.

Modifications of the extralabel provisions- A ten-year sunset clause may be excessive and serve as a disincentive to the pursuit of approvals. I feel that some individuals or groups will view this as a free allowed use for ten years just as some have viewed the use of therapeutants under compassionate INAD for aquaculture drugs. It should be emphasized that extended extralabel use will only be allowed if progress is being made on approval of the compound. A separate and shorter time limit should also be in place if no new progress is made for an NADA.

Expand established Congressional Research Funds - One major program that is not mentioned in this section that has been active in the pursuit of new approvals as well as extension and expansion of current approvals in aquaculture is the International Association of Fish and Wildlife Agencies Project (IAFWA). The Department of Interior (DOI), which has supplied base funding in conjunction with contributed funds from at least 30 state Fish and Wildlife Agencies, has suspended funding for this project at the end of FY98, even though this project has overwhelming support of the States and the U.S. Fish and Wildlife Service. While some new approvals will occur by the end of FY98 many of the Project drugs will be left short of any approvals while those drugs that do have new approvals will be limited. In order to have the broadest possible approval of compounds that the Project currently is working on, the DOI will need to maintain the base funding for this Project for an additional 4 years in addition to a renewal of financial backing from state Fish and Wildlife Agencies for an additional 3 years (Verbal commitment has already been made by the states for this extension). In addition the jeopardy of this program has further implications for other programs and individuals involved with aquaculture approvals. This includes the functioning of several aquaculture INADs; the IAFWA Project is also the largest single contributor to the salary of the National Aquaculture Coordinator.

My recommendation is that The DOI IAFWA Project also be included at a minimum of restored base funding for four years beyond FY98.

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